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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

PAPER NUMBER

3736

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |  |   |  |
|------------------------------|--|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/656,418   | <b>Applicant(s)</b><br>PARINS, DAVID J. |  |
|                              | <b>Examiner</b><br>JEFFREY G. HOEKSTRA | <b>Art Unit</b><br>3736                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 3-5, 12-14, 21, 22, 30, 31, 38, 39 and 44-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6-11, 15-20, 23-29, 32-37 and 40-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission(s) filed on 12/28/2009 and 12/29/2009 have been entered.

### ***Notice of Amendment***

2. In response to the amendment(s) filed on 12/28/2009 and 12/29/2009, the current rejections of the claim(s) 1, 6-11, 15-20, 23-29, 32-37, and 40-43 is/are *withdrawn*. The following reiterated ground(s) of rejection is/are set forth:

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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4. Claims 10, 15-17, 28, 32-34, 36, and 40-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Johansen et al. (US 7,303,533 B2, hereinafter Johansen).

5. For claims 10, 28, and 36, Johansen discloses and shows an intracorporeal device (10 and/or 20) comprising a guidewire (10 and/or 20), comprising *inter alia*:

- an elongate shaft (column 2 lines 48-52) inherently having a proximal end, inherently having an opposing distal end, and defining a longitudinal shaft axis extending along the shaft length between the proximal and distal ends;
- a helically wound coil (20) (as best seen in Figure 2) (column 3 lines 27-67) having a plurality of windings (24) (as best seen in Figure 2) (column 3 lines 27-67), inherently having an outer perimeter (the outer perimeter of helically wound coil 20 as best seen in Figure 2), inherently forming a coil length (the coil length of helically wound coil 20 as best seen in Figure 2), inherently having a proximal end, inherently having an opposing distal end, and defining a longitudinal coil axis extending along the coil length between the proximal and distal ends, and said coil length disposed about a portion of the distal end of the elongate shaft (column 2 lines 48-52); and
- a plurality of joining elements (22) (as best seen in Figure 2) (column 3 lines 27-67) longitudinally disposed on only a portion of the outer perimeter (as best seen in Figure 2) (as best seen in Figure 2) (column 3 lines 27-67) and longitudinally disposed along the coil length (as best seen in Figure 2) (column 3 lines 27-67),
- wherein each joining element is located at a longitudinal position along the coil length relative to the coil axis and only couples two or more coil windings (column 3 lines 27-67),

- wherein each joining element is a discrete element (as best seen in Figure 2) (column 3 lines 27-67),
  - wherein the longitudinal position at least one of the plurality of joining elements is longitudinally offset from at least the longitudinal position of at least one other joining element along the coil length as viewed from a direction traverse to the coil axis (as best seen in Figure 2) (the Examiner notes in Figure 2, each of the 3 welds are longitudinally offset from one another as viewed from a direction traverse to the coil axis),
  - wherein at least one of the plurality of joining elements is longitudinally spaced apart from at least one other joining element in a direction along the longitudinal axis (as best seen in Figure 2),
  - wherein at least one of the plurality of joining elements is disposed more distal than at least one other joining element (as best seen in Figure 2), and
  - wherein at least one of the plurality of joining elements is disposed closer to the proximal end than at least one other joining element (as best seen in Figure 2) with no longitudinal overlap in a direction along the longitudinal axis (as best seen in Figure 2) (the Examiner notes when looking down the coil along axis 26 the joining elements are spaced without overlap).
6. For claims 15, 32, and 40, Johansen discloses and shows the guidewire, wherein the joining elements form a uniform pattern of joining elements along the coil length (as best seen in Figure 2) (column 3 lines 27-67).

7. For claims 16, 33, and 41, Johansen discloses and shows the guidewire, wherein each joining element couples 3 to 10 coil windings (as best seen in Figure 2) (column 3 lines 27-67).

8. For claims 17, 34, and 42, Johansen discloses and shows the guidewire, wherein each joining element is a discrete element aligned orthogonal to the windings in a radial direction (as best seen in Figure 2) (column 3 lines 27-67).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1, 6-9, 11, 18, 29, 35, 37, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johansen et al. (US 7,303,533 B2, hereinafter Johansen).

11. For claims 1, 6-9, 11, 18, 29, 35, 37, and 43, Johansen discloses and shows the guidewire, as set forth and cited above, including the claim limitations of claims 6-8 (see paragraphs 4-7 above), except for expressly disclosing (a) the plurality of joining elements comprising at least ten joining elements disposed along the coil length and (b) each joining element has a width in the range of 0.1 to 0.5 mm and a length in the range of 0.1 to 1.5 mm.

12. For claims 1, 6-9, 11, 18, 29, 35, 37, and 43, as evidenced by Applicant "the number and size of the joining elements can be varied to obtain the desired characteristics". The Specification at at least pages 7-8 reads as follows:

- *"A plurality of joining elements 120 can be disposed along the coil length L. The joining elements couple a plurality of coil windings 105 together. Each joining element 105 may join from 2, 3, 4, 5, 6, 7, 8, 9, or 10 or more coil windings 105 together. There may be 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40 or more joining elements 120 disposed in a uniform or non-uniform pattern along the coil length. In at least some embodiments, the joining elements 120 may only function to join coil windings 105 together. For example, in at least some embodiments, the coil joining element or elements 120 join a plurality of coil windings 105 together, but do not act to join any other structure within the device 100. In such embodiments, the coil joining element or elements 120 act only to join coil windings 105 together, and do not join any other structure to the coil. For example, in some such embodiments, the joining elements 120 do not join the coil 110 to the shaft or core 130.*
- *"The joining elements 120, by interconnecting a series of coil windings, can provide enhanced torque transmission along the coil length L and/or enhanced push- ability while still providing flexibility that a coil 110 offers. The degree of enhanced torque transmission and/or push-ability is dependent at least in part on the number of joining elements along the length of the coil, and the size of each joining element (i.e. the number of coil windings joined be each joining element). Those of skill in the art, and others will recognize that as a general proposition, that greater enhanced torque transmission and/or push-ability can be achieved by using a greater the number of joining elements along a coil length, and/or by increasing the number of coil windings 105 joined by each joining element 120. The number and size of the joining elements 120 can be varied to obtain the desired characteristics.*
- *"In some embodiments, the joining elements 120 may have a length in the range of about 0.1 to about 1.5 mm and a width in the range of about 0.1 to about 0.5 ram. The joining elements 120 can be discrete elements aligned orthogonal to the coil windings 105 as illustrated in Fig. 1. The joining elements 120 may be formed of a material the same as or different from the coil 110. The coil*

*windings 105 define an outer perimeter 150. The joining elements 120 can be disposed about the outer perimeter 150 such that only a portion of the outer perimeter 150 is covered by joining elements 120. In some embodiments, each joining element 120 may be disposed on less than 1/10 of the total outer perimeter 150 of each winding 105."*

13. Thus for claims 1, 6-9, 11, 18, 29, 35, 37, and 43, Johansen discloses the claimed invention but does not disclose expressly the number and size of the joining elements as claimed. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the guidewire as taught by Johansen with the number and size of the joining elements as claimed, because Applicant has not disclosed that the number and size of the joining elements as claimed provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with configuration of the joining elements as taught by Johansen, because it provides for configuring the degree of stiffness, flexibility, and torqueability of the guidewire by altering the number of welds (i.e. joining elements) (column 3 lines 55-58) and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Johansen. Therefore, it would have been an obvious matter of design choice to modify Johansen to obtain the invention as specified in the claim(s).

14. Claims 19, 20, and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johansen et al. (US 7,303,533 B2, hereinafter Johansen) in view of Erickson et al. (US 5,664,580, hereinafter Erickson).



15. For claim 19, Johansen discloses and shows the guidewire, as set forth and cited above, except for expressly disclosing at least one joining element does not couple to any of the two or more coil windings coupled by the at least one other joining element.

16. For claim 19, Erickson teaches an intracorporeal device (10) (as best seen in Figures 1-2) comprising a guidewire (10) (as best seen in Figures 1-2), comprising *inter alia*: at least one joining element (column 5 line 56 – column 6 line 59) (as best seen in Figures 1-2) does not couple to any of the two or more coil windings (20) (column 5 lines 8-36) (as best seen in Figures 1-2) coupled by the at least one other joining element (column 5 line 56 – column 6 line 59) (as best seen in Figures 1-2).

17. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the guidewire coil joining element configurations are known in Johansen and Erickson. The only difference is the combination of the guidewire coil joining element configurations into a single guidewire configuration. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the guidewire coil joining element configurations as taught by Johansen with the guidewire coil joining element configurations as taught by Erickson to achieve the predictable results of increasing the efficacy of a guidewire coil to traverse tortuous vasculature by configuring the flexibility and/or torqueability of the coil by using an alternate guidewire coil joining element configuration.

18. For claims 20 and 26, Johansen in view of Erickson discloses and shows the guidewire, as set forth and cited above, except for expressly disclosing (a) the plurality of joining elements comprising at least ten joining elements disposed along the coil length and (b) each joining element has a width in the range of 0.1 to 0.5 mm and a length in the range of 0.1 to 1.5 mm.

19. For claims 20 and 26, as evidenced by Applicant “the number and size of the joining elements can be varied to obtain the desired characteristics”. The Specification at at least pages 7-8 reads as follows:

- *“A plurality of joining elements 120 can be disposed along the coil length L. The joining elements couple a plurality of coil windings 105 together. Each joining element 105 may join from 2, 3, 4, 5, 6, 7, 8, 9, or 10 or more coil windings 105 together. There may be 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40 or more joining elements 120 disposed in a uniform or non-uniform pattern along the coil length. In at least some embodiments, the joining elements 120 may only function to join coil windings 105 together. For example, in at least some embodiments, the coil joining element or elements 120 join a plurality of coil windings 105 together, but do not act to join any other structure within the device 100. In such embodiments, the coil joining element or elements 120 act only to join coil windings 105 together, and do not join any other structure to the coil. For example, in some such embodiments, the joining elements 120 do not join the coil 110 to the shaft or core 130.*
- *“The joining elements 120, by interconnecting a series of coil windings, can provide enhanced torque transmission along the coil length L and/or enhanced push- ability while still providing flexibility that a coil 110 offers. The degree of enhanced torque transmission and/or push-ability is dependent at least in part on the number of joining elements along the length of the coil, and the size of each joining element (i.e. the number of coil windings joined be each joining element). Those of skill in the art, and others will recognize that as a general proposition, that greater enhanced torque transmission and/or*

*push-ability can be achieved by using a greater the number of joining elements along a coil length, and/or by increasing the number of coil windings 105 joined by each joining element 120. The number and size of the joining elements 120 can be varied to obtain the desired characteristics.*

- *"In some embodiments, the joining elements 120 may have a length in the range of about 0.1 to about 1.5 mm and a width in the range of about 0.1 to about 0.5 mm. The joining elements 120 can be discrete elements aligned orthogonal to the coil windings 105 as illustrated in Fig. 1. The joining elements 120 may be formed of a material the same as or different from the coil 110. The coil windings 105 define an outer perimeter 150. The joining elements 120 can be disposed about the outer perimeter 150 such that only a portion of the outer perimeter 150 is covered by joining elements 120. In some embodiments, each joining element 120 may be disposed on less than 1/10 of the total outer perimeter 150 of each winding 105."*

20. Thus for claims 20 and 26, Johansen in view of Erickson discloses the claimed invention but does not disclose expressly the number and size of the joining elements as claimed. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the guidewire as taught by Johansen in view of Erickson with the number and size of the joining elements as claimed, because Applicant has not disclosed that the number and size of the joining elements as claimed provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with configuration of the joining elements as taught by Johansen in view of Erickson, because it provides for configuring the degree of stiffness, flexibility, and torqueability of the guidewire by altering the number of welds (i.e. joining elements) (Johansen, column 3 lines 55-58) and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Johansen in view of Erickson.

Therefore, it would have been an obvious matter of design choice to modify Johansen in view of Erickson to obtain the invention as specified in the claim(s).

21. For claims 23-25 and 27, Johansen discloses and shows the guidewire including the claim limitations of claims 23-25 (see paragraphs 4-7 above) and for claim 27, Johansen discloses and shows the guidewire, wherein each joining element is disposed on less than 1/10 of the outer perimeter of each winding (as best seen in Figure 2).

### ***Response to Amendment***

22. The declaration filed on 12/28/2009 under 37 CFR 1.131 has been considered but is ineffective to overcome the Johansen et al. reference (US 7,303,533 B2).

23. MPEP 715, especially section 715.07 III, explicitly states with respect to antedating a reference using a 1.131 declaration to show prior invention, in part, the following:

- “The showing of facts must be sufficient to show:
  - > (actual)< reduction to practice of the invention prior to the effective date of the reference; or
  - conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to a subsequent (actual) reduction to practice; or
  - conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to the filing date of the application (constructive reduction to practice).”;
- “Conception is the mental part of the inventive act, but it must be capable of proof, as by drawings, complete disclosure to another person, etc.”; and
- “In general, proof of actual reduction to practice requires a showing that the apparatus actually existed and worked for its intended purpose.”

24. The declaration filed 12/28/2009 *fails to provide proof of an actual reduction to practice* prior to the effective date of the reference because there is *no showing that the apparatus actually existed or that it worked for its intended purpose*. Conversely, the exhibit relied upon, comprising invention disclosure # 03-00071 of Scimed Life Systems, Inc., appears to *show a scope of a "process" or "method" of fabricating a guidewire element*. The exhibit is not an actual prototype of the claimed device, nor does it even describe one. The exhibit does not appear directed to a “device” or “apparatus”.

25. The declaration filed 12/28/2009 fails to provide proof of conception of the claimed device prior to the effective date of the reference and moreover fails to provide due diligence from prior to the reference date to a subsequent actual reduction to practice.

26. Furthermore, the Examiner notes the exhibit, directed towards a method of fabrication of solely a coil having soldered zone portions, does not appear commensurate with the scope of any of the pending claims and the declaration does not attempt to describe and/or explain the relationship between the exhibit and the claimed limitations.

### ***Response to Arguments***

27. Applicant's arguments filed 12/29/2009 have been fully considered but they are not persuasive.

28. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically

pointing out how the language of the claims patentably distinguishes them from the references.

29. Applicant's arguments are merely directed towards antedating the Johansen et al. reference (US 7,303,533 B2) as prior art via the declaration of prior-invention filed under 35 U.S.C. 1.131. Applicant's attention is respectfully directed to the Response to Amendment section hereinabove.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey G Hoekstra/  
Examiner, Art Unit 3736